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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,579	01/25/2001	Hector F. DeLuca	960296.95700	4517

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/769,579	Applicant(s) DELUCA ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment filed on February 25, 2002 has been entered. Claims 1-10 are pending.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over EURODIAB (PTO-892, filed 10/10/01) in view of Mathieu et al (IDS, Paper No. 4) Mauricio et al (PTO-892, filed 10/10/01) and DeWille et al (US 5,817,351; PTO-892, filed 10/10/01).

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the rejection of claims 1-5 are based on combined teachings of the cited references not the teachings of anyone individual reference.

Applicant arguments that the cited reference are describing ordinary Vitamin D is noted, but not persuasive, because the term vitamin D generically describes all steroids that exhibit qualitatively the biological activity of cholecalicfeol (see Dictionary of Biochemistry Molecular biology, 2nd ed. 1991, John Willey & Son). Accordingly, 1 α-

hydroxyvitamin D is encompassed by such definition of vitamin D and additionally is well recognized in the art as a potent analog of vitamin D (see Jones, Exhibit A of the amendment, page 974, 1st col, and its reference 41).

Further, Applicant's assertion that the cited art describe "ordinary vitamin D" is not understood, as all vitamin D within its generic meaning are expected to provide similar clinical benefit. In fact, Muricio explicitly teaches the beneficial use of the instant species with the genus of vitamin D; therefore using vitamin D for delaying the onset of diabetes is well established. Examiner does not dispute that various vitamin D analogs may provide different degree of efficacy in vivo, however, the instant claims are not directed to any different degree of efficacy, and such argument would not be commensurate with the scope of the pending claim.

As stated in the previous Office Action, Paper No. 5, the teachings of EURODIAB, Mathieu and Muricio et al collectively provides the understanding in the art that vitamin D and analogues thereof, including 1, α-hydroxyvitamin D_3, improves the symptoms of autoimmune diseases and diabetes (see EURODIAB, abstract; Mathieu, pp 552-556; Muricio et al pp 64, 1st col, 2nd paragraph). DeWille provides that all vitamin D such as 1 α vitamin D can be prepared and used orally, thus, it would have been obvious to one of ordinary skill in the art at the time of invention to use 1 α vitamin D for diabetes as well. Accordingly, the combination of cited references render the instant claims obvious.

Furthermore, an obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed

compound, in the expectation that compounds similar in structure will have similar properties. In re Payne,606 F.2d 303, 313, 203 USPQ 245, 54 (CCPA 1979). In the instant case, the useful ness of generic vitamin D encompassing 1-α hydroxyvitamin D3 is well established by EURODIAB. Mathieu used 1,25 α dihydroxyvitamin D_3 for preventing insulitis. Maricio specifically recites similar type utility with 1-α hydroxyvitamin D_3, thus, one of ordinary skill in the art would have had a reasonable expectation to observe similar benefits from other structurally similar compounds including 1 α-hydroxyvitamin D_3. Finally, route of administration is a matter of design choice and well within purview of the ordinary artisan.

Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Qadreh et al (PTO-892, filed on 10/10/01) in view of DeWille et al (US 5,817,351; PTO-892 filed on 10/10/01).

Applicant's arguments with respect to this rejection have been considered but are not found persuasive.

Applicant argues that the instant claims are directed towards oral administration and none of the references teach the oral administration of 1- α hydroxyvitamin D3 for treament of diabetes.

Again Examiner states that the rejection is based on the combination of teachings of the cited references, not their individual teachings. Al-Qadreh teaches that the instantly claimed compounds are effective in treating insulin-dependent diabetes mellitus. Accordingly, Al-Qadreh principally suggest that higher systemic serums of the instant compounds improves diabetes associated symptoms such as osteopoenia,

regardless of route of administration. DeWille teaches that Vitamin D 3 can be administered orally to provide its systemic effects. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention armed with the combined teachings of Al-Qadreh and DeWillie to have expectation of successful results if Vitamin D3 is administered orally.

Conclusion

No claims are allowed.

Examiner noted that recitations such as "delaying the onset of diabetes," "the onset of diabetes or diabetes symptoms is slowed," "reducing the severity of diabetes symptoms," or "diabetes symptoms are lessened" in claims 1 and 6 appear to be of relative nature and do not clearly define the scope of the claims. Clearing the scope of such limitations could advance the prosecution of the claims over the cited prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, JD can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

ss
May 10, 2002